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July 17, 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Re: U.S. Patent Application No. 10/576,857 filed April 20, 2006  
Applicant: Hans Lennernas, et al.  
Title: **COMPOSITION COMPRISING BIODEGRADABLE HYDRATING  
CERAMICS FOR CONTROLLED DRUG DELIVERY**  
Group Art Unit:  
Attorney Docket No. 02314-22135

Sir/Madam:

Transmitted herewith for filing and pursuant to 37 C.F.R. §§ 1.56 and 1.97 is an Information Disclosure Statement. Enclosed also are the following designated documents, as required under 37 C.F.R. §§ 1.97 and 1.98:

- ☒ Form PTO/SB/08A and PTO/SB/08B list of 43 references submitted for consideration.
- ☐ Legible copies of the listed references or their relevant portions.
- ☒ Legible copies of the listed non-patent documents and foreign documents or their relevant portions are included.
- ☒ Copies of U.S. patents and/or publications are not included pursuant to the Official Gazette Notice, dated Aug. 5, 2003, waiving the requirement of 37 C.F.R. 1.98(a)(2)(i).
- ☐ All English translations of each non-English reference, if any, within the possession, custody, control or availability of anyone designated in 37 C.F.R. § 1.56(c) (see 37 C.F.R. § 1.98(c)).

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The following are included within the Information Disclosure Statement if applicable and as required under 37 C.F.R. § 1.98:

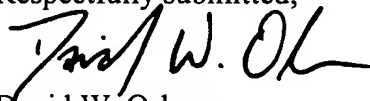
- ☐ Concise explanation of relevance of each reference not in English and unaccompanied by an English translation.
- ☐ Statement that certain listed references not enclosed are substantially cumulative of an enclosed reference.
- ☐ Statement that certain listed references not enclosed were previously cited by or submitted to the Office in prior application no. \_\_\_\_\_, filed on \_\_\_\_\_, which is relied upon for an earlier filing date under 35 U.S.C. § 120.

In order to secure consideration of the items designated above, one or more of the following, if required, is also enclosed:

- ☐ Statement under 37 C.F.R. § 1.97(e)(1) or (2).
- ☐ Check No. \_\_\_\_\_, which includes the amount of \$180.00 (amount in § 1.17(p)) constituting the submission fee set forth in 37 C.F.R. § 1.17(p).

In the event that 37 C.F.R. § 1.97(c) applies and the Examiner is not satisfied that the Statement meets the requirements of 37 C.F.R. § 1.97(e), or in any other event remediable by a fee, please credit any over payment or charge any additional fees to Deposit Account No. 20-0100 of the undersigned.

Respectfully submitted,



David W. Osborne  
Attorney for Applicant  
Registration No. 44,989

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DWO/jlp



IN THE UNITED STATES PATENT & TRADEMARK OFFICE

ART UNIT:  
EXAMINER:  
APPLICANT: Hans Lennernäs  
SERIAL NO.: 10/576,857  
FILED: April 20, 2006  
CONFRM. NO.:  
FOR: COMPOSITION COMPRISING  
BIODEGRADABLE HYDRATING  
CERAMICS FOR CONTROLLED  
DRUG DELIVERY  
DOCKET NO.: 02314-22135

**CERTIFICATE OF MAILING**  
**UNDER 37 C.F.R. § 1.8**

DATE OF DEPOSIT: 7/18/2006

I hereby certify that this paper or fee (along with any paper or fee referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail on the date indicated above and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

  
Jennifer Pogue

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir/Madam:

Please find, pursuant to 37 C.F.R. § 1.98(a)(1), the enclosed Form **PTO/SB/08A** and **PTO/SB/08B** which contains a list of all patents, publications, or other items that have come to the attention of one or more of the individuals designated in 37 C.F.R. § 1.56(c). Applicant respectfully submits that this Information Disclosure statement is filed pursuant to:

☒ 37 C.F.R. § 1.97(b)(1) or (3), within three months of the filing date of the application, or before a first office action on the merits, whichever occurs last;

☐ 37 C.F.R. § 1.97(c), after a first office action on the merits, but before a Final Office Action or a Notice of Allowance, whichever occurs first, and is accompanied by either 1) a statement in accordance with 37 C.F.R. § 1.97(e), or 2) the fee set forth in 37 C.F.R. § 1.17(p); or

☐ 37 C.F.R. § 1.97(d), after a Final Office Action or Notice of Allowance, whichever occurs first, but on or before payment of the issue fee, and is accompanied by both 1) a statement in accordance with 37 C.F.R. § 1.97(e), and 2) the fee set forth in 37 C.F.R. § 1.17(p).

While no representation is made that any of these references may be "prior art" within the meaning of that term in accordance with 37 C.F.R. §§ 102 or 103, the enclosed list of references is disclosed so as to comply with the duty of disclosure set forth in 37 C.F.R. § 1.56.

Moreover, while no representation is made that a specific search of office files or patent office records has been conducted or that no better art exists, the undersigned attorney of record believes that the references listed, together with any other references which may have been previously submitted or listed, are the closest to the claimed invention (taken in its entirety) of which the undersigned is presently aware, and no art which is closer to the claimed invention (taken in its entirety) has been knowingly withheld.

☐ A legible copy of each listed U.S. Patent or publication (or relevant portion thereof) which was not previously submitted to, or cited by, the Patent Office is enclosed pursuant to 37 C.F.R. §§ 1.97 and 1.98.

☒ A legible copy of each of the listed non-patent literature and foreign documents or their relevant portions is enclosed.

☒ Copies of cited U.S. patents and/or publications are NOT enclosed pursuant to the Official Gazette Notice, dated August 5, 2003, waiving the requirement of 37 C.F.R. § 1.98(a)(2)(i).

☐ Copies of the references listed in the accompanying Form PTO/SB/08A and PTO/SB/08B are NOT enclosed because, under 37 C.F.R. § 1.98.(d), they were previously cited by or submitted to the Office in application number \_\_\_\_\_, which is relied upon for an earlier filing date under 37 C.F.R. § 1.20.

For all listed references that are not either in the English language, or accompanied by a translation into English, a concise explanation of relevance as required under 37 C.F.R. § 1.98(a)(3) is enclosed attached to each.

The Commissioner is hereby authorized to charge any additional fees associated with this communication or to credit any overpayment to Deposit Account No. 20-0100.

Dated July 17, 2006.

Very truly yours,

A handwritten signature in black ink, appearing to read "David W. Osborne".

David W. Osborne  
Attorney for Applicant  
Registration No. 44,989

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Customer No. 20,551  
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DWO/jlp  
Enclosures



PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)		Application Number	10/576,857
		Filing Date	April 20, 2006
		First Named Inventor	
		Art Unit	
		Examiner Name	
Sheet	of	Attorney Docket Number	02314-22135

#### U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-6869976	03-22-2005	Royer Biomedical inc.	
		US-6630486	10-07-2003	Royer Biomedical inc.	
		US-6391336	05-21-2002	Royer Biomedical inc.	
		US-2004/020893	02-05-2004	Royer Biomedical inc.	
		US-6277391	08-21-2001	M. H. Seo et al.	
		US-4891225	01-02-1992	R.S. Langer et al.	
		US-5626862	05-06-1997	H. Brem et al.	
		US-2003/147936	08-07-2003	S. Velayudhan	
		US-4218255	08-19-1980	University of Dayton	
		US-5156623	10-20-1992	Y. Hakamatsuka et al.	
		US-5614206	03-25-1997	D.A. Randolph et al.	
		US-5683725	11-04-1997	S. Malik et al.	
		US-5756127	05-26-1998	B.F. Grisoni et al.	
		US-5807567	09-15-1998	D.A. Randolph et al.	
		US-6251139	06-26-2001	C. Lin et al.	
		US-6497901	12-24-2002	Royer Biomedical inc.	
		US-6689375	02-10-2004	H. Wahlig et al.	
		US-2003/170307	09-11-2003	Royer Garfield P	
		US-5164186	11-17-4992	Tsuru et al.	
		US-2003/082232	05-01-2003	Mundipharma GMBH	
		US-6030636	02-29-2000	Randolph et al.	

#### FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>2</sup> - Number <sup>3</sup> - Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		WO 0241844	05.30.2002	Etex Corp.		
		EP 0376331	07.04.1990	Asahi Kogaku Kogyo		
		WO 99/15150	04.01.1999	Buford Biomedical inc.		
		WO 04/000276	12.31.2003	Royer Biomedical inc.		
		WO 04/000277	12.31.2003	Royer Biomedical inc.		
		DE19620117	07.24.1997	Corimed Kundenorientierte Medicinprodukte GmbH		
		EP 0159089	10.23.1985	Stitching Biomaterials Science Center		
		EP 0508653	10.14.1992	Tanabe Seiyaku Co. Ltd.		
		WO 00/045734	08.10.2000	Wright Medical Technology inc.		
		WO 01/05706	01.25.2001	Biocomposites Ltd.		
		WO 02/087649	11.07.2002	Biocomposites Ltd.		
		WO 03/011214	02.13.2003	G. Royer et al.		
		WO 03/011957	02.13.2003	BioloK International inc.		

	WO 03/024316	02.13.2003	Stryker corp.		
	WO 03/043607	05.30.2003	H. Sen et al.		
	WO 03/059409	07.24.2003	Biocomposites Ltd.		
	WO 03/092759	11.13.2003	Japan Science and technology corp. et al.		
	WO 04/028580	04.08.2004	Regen Biotec inc.		
	WO 97/47334	12.18.1997	Bioland		
*	EP 0947489	06.10.1999	Kabushiki Kaisya Advance		
	EP 0192068	27.08.1986	The Dow Chemical Company		
	EP 0061108	29.09.1982	Mundipharma Strasse		

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.